America's pharmaceutical research companies: Keeping the cost of health care down

Pharmaceutical Manufacturers Association

A response to the staff report of the U.S. Senate Special Committee on Aging.

The staff of the U.S. Senate Special Committee on Aging issued a report on September 24, 1991 intended for informational purposes. "It does not represent either findings or recommendations formally adopted by the Committee," according to the report.

The report is critical of America's pharmaceutical research companies on 5 principal points: prices, profits, marketing, research and tax credits.

The staff report is biased and replete with factual errors, erroneous interpretations and misstatements. Then, on the basis of flawed findings, the report presents misguided policy options.

America's pharmaceutical industry leads the rest of the world in innovation; the new drugs that are developed by the industry improve the health and quality of life of patients here and around the world. These medicines save lives and money. They often cure or control deadly diseases, shorten hospital stays, reduce physician visits and obviate surgery in millions of cases. Prescription medicines help hold down health-care costs. And they are the best hope for containing health-care costs in the future.

The following addresses the report's principal allegations.

Prescription drug prices/profitability

Costs of discovering and developing pharmaceuticals have risen sharply.

- Industry-funded research and development expenditures have doubled every 5 years since 1970, reaching $9.2 billion in 1991 — more than the total invested in biomedical research by all the National Institutes of Health.
- Drug prices have not risen as fast as the industry's R&D expenditures. In 1990, for example, the rise in pharmaceutical research was virtually double the rate of drug price increases across the industry.
- Compared with all other U.S. industries, the pharmaceutical industry devotes a higher percentage of sales revenues to R&D — 16.5% in 1990 for all PMA member companies. This is more than 4 times the average of all industries.
- The latest estimate — by economists at Tufts University — of the cost of developing a new drug is $231 million, up sharply from earlier estimates.
- A recent study by Duke University economist Henry Grabowski found that only 3 of every 10 drugs introduced by the pharmaceutical industry between 1970 and 1979 subsequently recovered their R&D costs.
- The Grabowski study also concluded that if prices had risen at only the general rate of inflation since 1980, the industry could not have recovered its costs for this portfolio of drugs and R&D expenditures would have been adversely affected.

The 1980s have seen greatly shortened product life cycles for pharmaceuticals.

- In 1984, the life cycle of pharmaceutical products that had lost patent protection was shortened dramatically with the passage of the Drug Price Competition and Patent Term Restoration Act (Waxman-Hatch), which made possible quick approval of generic copies of brand-name products. Within 2 years of patent expiration, the typical pharmaceutical product now loses half of its market. This has put significant pressure on prices.

Foreign patent piracy raises costs.

- Countries such as India, Brazil and Thailand steal an estimated $4.8 billion in patented inventions from U.S. pharmaceutical companies each year, according to the U.S. Trade Representatives and the International Trade Commission.

A different Consumer Price Index (CPI) base year would lead to different conclusions.

- To demonstrate that pharmaceutical price increases are advancing faster than other medical expenditures, the report uses 1980 as a base year. If the report had gone back to the CPI's previous base year of 1967, it would show that drug prices lagged behind the all-items CPI until 1990 — and still trails the CPI's medical component by 200 points. (See chart.)

(Continued) ➤

Pharmaceutical Manufacturers Association
1100 Fifteenth Street, NW
Washington, DC 20005

Received for publication October, 1991.

- Regardless of what the report implies, the average cost of a prescription drug in the U.S. in 1990 was $19.94.

U.S. versus Canadian prices.

- Canadian prescription-drug prices vary from province to province, depending on many factors. Ontario, for example, will pay for only the cheapest generic drugs for its elderly and indigent residents. A similar approach for Medicaid was proposed by Senator Pryor last year and soundly rejected.
- Canada is the only Western industrialized nation that links the market exclusivity of a patented product to its price. Adopting such a patent-crippling system in the United States would have the same effect in this country as Canada's traditionally weak patent system has had in Canada. It would impair the U.S. pharmaceutical industry's innovativeness, making it far less competitive with drug industries in other industrialized countries, such as the United States, Japan, Germany and Switzerland, where patent laws are strong.
- The staff report fails to mention that Canada is the major industrial country with the weakest condition for pharmaceutical innovations, having contributed the least number of new compounds in recent years to cure diseases. Those who advocate Canada's system of price controls and weak patent protection invite a rapid decline in American pharmaceutical innovation, with disastrous consequences for the health of our citizens.

Pharmaceutical industry profitability

- Investments in high-risk ventures — such as new drug development, where fewer than 1 in 5,000 chemicals or biologicals tested actually is ever marketed — appropriately require a rate of return considerably higher than could be obtained from placing the same money in an average company.

Pharmaceutical industry marketing

Marketing practices conform to AMA guidelines

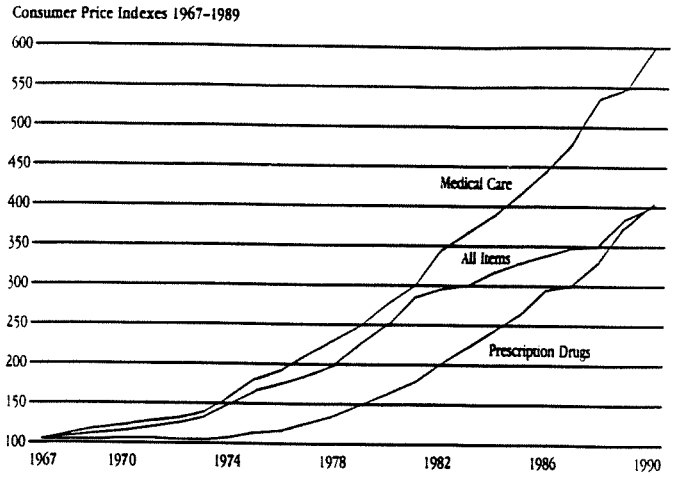
- The staff report's examples of "abusive marketing and promotional practices" do not reflect today's market. Pharmaceutical promotional practices conform to guidelines adopted by the American Medical Association's House of Delegates on December 4, 1990, which the PMA Board of Directors adopted 2 days later. Since the guidelines forbid the practices cited in the report, legislative remedies are unnecessary.

Pharmaceutical industry research

Drug industry breakthrough research

- The report asserts that "few breakthrough drugs" have resulted from the drug industry pricing policies that have sustained research and development. This ignores dozens of "break-through" drugs in past decades. They include biotechnology breakthroughs such as human growth hormone for dwarfism, interferon alpha for AIDS-related Kaposi's sarcoma, erythropoietin for dialysis-associated anemia and granulocyte colony stimulating factor for chemotherapy-induced neutropenia (low white blood cell count). It flagrantly ignores the many breakthrough "conventional" drugs and vaccines for diseases such as river blindness, African sleeping sickness, malaria, severe combined immunodeficiency disease (the so-called "Bubble Boy" disease), AIDS-associated cytomegalovirus retinitis, AIDS-associated cryptococcal meningitis and systemic candidal infections, hepatitis B, haemophilus influenza type B, and neonatal respiratory distress syndrome. And the R&D pipeline is bursting with future breakthroughs.
- The report shows little appreciation of the value of the second or third products on the market in a therapeutic category. These products, though perhaps not breakthroughs, often offer major advances in treatment and reduction in side effects. Examples include newer cephalosporin antibiotics requiring less frequent administration and enabling home intravenous use; improved cancer chemotherapeutic agents which eliminate hospitalization, and newer medications effective in the treatment of schizophrenia and depression.

Rx Drug Prices Below Other Indices



Source: Bureau of Labor Statistics

There are better ways to lower cost of providing needed medicines

Policy options which might actually help reduce the cost of prescription drugs are:

- *Streamline the drug approval process.* The average cost of getting a drug onto the U.S. market could be cut substantially if clinical testing and FDA review times were reduced to that experienced in major European countries such as the United Kingdom.
- *Reduce patent piracy.* U.S. research-based pharmaceutical companies lose about $5 billion a year to international patent pirates, who copy their drugs without per-

(Continued on page 19) ➤

HEREDITARY ANEMIA *(Continued from page 17)*

11. Hsia YE, Yuen J, Hunt JA, Chu BM, Miyakawa F: Hemoglobin H is not a disease. *Pediatr Res* 29:131A, 1991 [#769].
12. Hsia Ye, Yuen J, Hunt JA, Rattamanasay P, Hall J, Takaesu N, Titus EAB, Fujita J, Ford CA: The different types of alpha-thalassemia: practical and genetic aspects. *Hemoglobin* 12:465-484, 1988.
13. Ireland JH, Hsia YE, Chui DHK: Anti-zeta testing for alpha-1 thalassemia in newborns. *Pediatr Res* 29:142A, Abstr 841, 1991.
14. Ireland JH, Hsia YE, Chui DHK: Anti-zeta screenign detects the (--SEA) double alpha-globin deletion. *Am J Hum Genet* 46:A329, 1991 [1839].
15. Yuen J, Hsia YE: Consumer attitudes toward thalassemia screening: heterozygotes of multi-ethnic origin. *Am J Hum Genet* 46:A331, 1991 [1851].
16. Yuen J, Hsia YE: How community resources can be utilized in multi-ethnic population screening — a thalassemia screening model. *Am J Hum Genet* 42:282A, 1989 #1113.
17. Yuen J, Hsia YE, Hall J: Impact of a thalassemia screening program on the attitudes of a multi-ethnic poulation. *In:* Bank A (ed): Sixth Cooley's Anemia Symposium. *New York Acad Sci* 612:529-531.
18. Yuen J, Hsia YE, Hall J: Thalassemia heterozygotes in Hawaii: ethnic attitudes toward screening and prenatal diagnosis. *Hemoglobin* 12:801-816, 1988.

■

PHARMACEUTICAL *(Continued from page 16)*

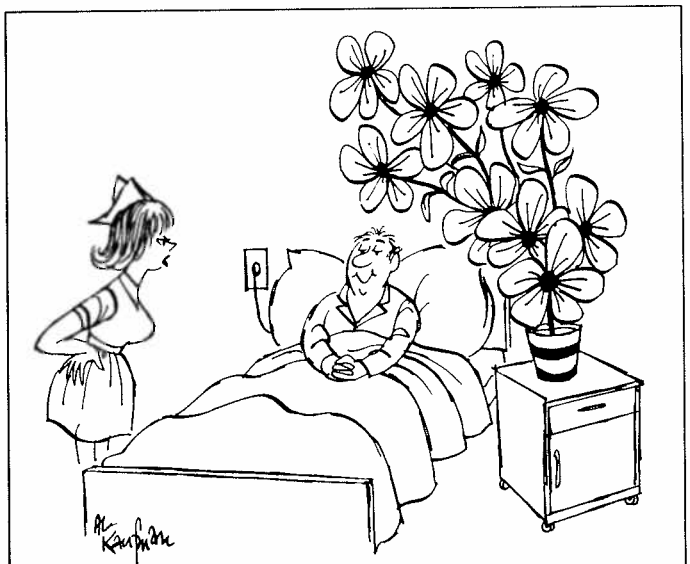
mission. Intellectual property protection must be strengthened, not weakened as in Canada, and tough action taken against patent pirates.

- *Cut product liability costs.* The high cost of protecting against the possibility of high jury awards in product liability cases adds millions of dollars to drug costs. A reform of the tort laws is needed, including protection against punitive damages for products that have been deemed safe and effective by the Food and Drug Administration.

Conclusion

The Senate Aging Committee's staff is singling out one competitive industry for price controls and weakened patent protection. If their recommendations are enacted, it would have a damaging effect on both health care and U.S. international competitiveness.

■



"ARE YOU SURE YOU'RE TAKING THAT VITAMIN PRESCRIPTION?"